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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,824	05/14/2001	Kristin J. Godbey	56466USA.002	9149

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Attention: Christopher D. Gram  
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EXAMINER

HOWARD, SHARON LEE

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/01/2002

3

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/854,824

Applicant(s)

GODBEY ET AL.

Examiner

Sharon L. Howard

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 August 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 40-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**Examiner acknowledges receipt of IDS filed on 8/13/01.**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-39, drawn to a device and a system for delivering at least one active agent to a localized body surface, classified in class 424, subclasses 443 and 448.
- II. Claims 40-44, drawn to a method of making a device for delivery of at least one active agent to a localized body surface, classified in class 424, subclasses 61,70.1,434,448.
- III. Claims 45-50, drawn to a method of delivering at least one active agent to a localized body surface, classified in class 424, subclasses 61,70.1,448.

The inventions are distinct, each from the other because there is no relation between a method of making a device for delivery of at least one active agent to a localized body surface and a method of delivering at least one active agent to a localized body surface.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Christopher Gram on September 25, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-39. Affirmation of this election must be made by applicant in replying to this

Art Unit: 1615

Office action. Claims 40-50 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

The abstract of the disclosure is objected to because of the inclusion of the word "said". Correction is required. See MPEP § 608.01(b).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5,9,13,38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. On page 7, line 13, applicant fail to disclose the derivatives of collagen and gelatin. On page 8, line 1, applicant fail to disclose the derivatives of alkoxyated derivatives. On page 7, line 13, applicant fail to disclose the polysaccharide derivatives.

### **DETAILED ACTION**

#### ***Claim Rejections - 35 USC § 103***

Art Unit: 1615

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garbe et al. (U.S. Patent No. 5,688,523) in view of Scholz et al. (U.S. Patent No. 6,019,997).

Garbe teaches a pressure sensitive skin adhesive sheet material comprising a liquid and a base layer which comprises a polymer (col.2, lines 53-66). Garbe teaches that the adhesive sheet comprises a water-soluble carrier comprising addition polymers (e.g. acrylates) (col.3, lines 4-10) and liquid excipients which include polyethylene glycol, polyethylene oxide and propylene glycol which can read on plasticizers (col.4, lines 47-63). Garbe discloses a backing film (col.3, lines 31-40).

Garbe does not teach an active agent.

However, Scholz teaches hydroalcoholic compositions comprising pharmaceutical active agents (i.e. antibacterials, steroids) (col.16, lines 44-67, bridging col.17, lines 1-27) which are known for treating skin conditions. Scholz teaches that the compositions can be used in transdermal delivery systems (e.g. devices) and can be placed within a polymeric material such as an adhesive (col.17, lines 28-67, col.18, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Garbe in the manner taught by Scholz.

One having ordinary skill in the art would have been motivated to modify the composition of Garbe to include an active agent, because Scholz teaches compositions comprising active agents which can be used in transdermal devices and an adhesive.

The expected result would be a device for delivering an active agent to a localized body surface comprising a water-soluble carrier comprising a polymer and a plasticizer, a water-soluble adhesive and a support layer.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3121 for regular communications and (703) 305-3592 for After Final communications.

Application/Control Number: 09/854,824  
Art Unit: 1615

Page 6

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

*Sharon Howard*

Sharon Howard  
September 28, 2002

*Thurman K. Page*  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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